

### REMARKS

Claims 1, 4-12, 15, 16 and 18-34 remain pending in the present application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

The drawings have been objected to as failing to comply with 37 CFR § 1.121(d). It appears that the Examiner is referring to the drawings originally filed with the present application. Additional copies of the corrected drawings originally filed on December 4, 2003 are enclosed herewith to address this objection. It is respectfully submitted that these drawings fully comply with 37 CFR § 1.121 and that this objection should be withdrawn.

Claims 1, 4-6, 8, 15 and 33 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,991,745 to Brown. 3/7/06 *Office Action*, p. 3.

Claim 1 recites a valve comprising "a first flexible member formed as a first sheet of polymeric material including first and second flaps separated from one another by a first slit, the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter, the first and second flaps remaining closed at all times when a fluid pressure exerted thereagainst is less than the threshold level to prevent flow through the first lumen" and "*a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position.*"

Brown describes a valve including a slit surrounded by a circular groove 4 and a set of ribs 7 extending radially from a center area of the valve. *Brown*, col. 6, lines 1-14. The ribs 7 are described as stiffening the center valve area. *Id.*, col. 6, lines 46-50. However, it is respectfully submitted that the ribs 7 stiffen the valve area only relative to areas from which material has been removed -- i.e., portions of the valve which are thinner than the ribs 7. The valve of Brown is integrally molded including the ribs 7 and the grooves 4. No separate member or additional material is added to the valve to form the ribs 7. Brown specifically states that the valve is integrally molded to provide "a unitary one-piece construction" and the ribs 7 are formed with a thickness equal to the center valve area. *Id.*, col. 5, lines 42-43 and col. 6, lines 44-47. Thus, the ribs 7 are merely an extension of the center valve area and are formed of the same

thickness of the same material as the rest of the valve. Because the ribs 7 are only a label for a specific portion of the valve and completely indistinguishable therefrom in terms of material characteristics, it is respectfully submitted that the ribs 7 do not constitute "biasing member[s] coupled to the first flexible member," as recited in claim 1. Furthermore, it is respectfully submitted that these ribs 7 also provide no biasing force beyond that supplied by the material of the valve itself, "biasing the first and second flaps toward the closed position," as recited in claim 1.

It is therefore respectfully submitted that claim 1 is allowable and that claims 4-6, 8, 15 and 33 depending therefrom are also allowable.

Claims 29 and 31 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Brown. 3/7/06 *Office Action*, p. 4. The Examiner stated, in support of the rejection, that Brown shows the invention substantially as claimed, except for the threshold pressure of the valve, but that it would have been obvious to one of ordinary skill in the art to alter the valve to achieve a desired threshold pressure.

Initially it is noted that as described above in regard to claim 1, Brown neither shows nor suggests a "first biasing member coupled to the first flexible membrane," and that these claims are allowable for the same reason. Furthermore, claims 29 and 31 recite limitations relating to pressures to which the valve will be subjected by anatomical influences. Brown's valve is described solely in conjunction with fluid dispensing packages and is unsuitable for use in medical devices. The valve described by Brown operates under pressures exerted by manual squeezing of the dispensing packages and is designed to remain closed at all times when not subject to this manually exerted pressure. It is respectfully submitted that the pressures which the valve of Brown are to resist greatly exceed those to which the valve of the present invention will be subjected -- i.e., those pressures exerted by anatomical processes.

It is therefore respectfully submitted that claims 29 and 31 are allowable over Brown for at least the reasons stated above in regard to claim 1.

Claim 7 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Brown in view of U.S. Patent No. 3,621,557 to Cushman et al. (Cushman). 3/7/06 *Office Action*, p. 4.

As discussed above, Brown does not teach or suggest "a first biasing member coupled to

the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1. Cushman describes an insert for a sandwich panel including a skin sheet 26 and a valve designed to remain sealed at all times regardless of a fluid pressure to which it is subjected. A spring 46 of the sandwich panel maintains the position of the insert by preventing lateral movement, keeping a top of the sandwich panel flush with the skin sheet 26. *Cushman*, col. 3, lines 70-75. The spring 46 does not participate in any way in the closing of the valve. In fact, the spring 46 is coupled to a cylindrical body of the insert and exerts no force whatsoever on the valve. The valve is a disc fitted against a metal washer. *Id.*, col. 3, lines 48-51. Therefore, the valve is isolated from any possibility of being acted upon by the spring 46, which cannot properly be considered a biasing member as recited in claim 1, from which this claim depends. Thus, it is respectfully submitted that Cushman is insufficient to cure the deficiencies of Brown and neither Brown nor Cushman combination, discloses or suggests "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1 and claim 7 is allowable over these references applied individually or in combination.

Claims 9-12, 16, 18, 22-27, 30, 32 and 34 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,810,789 to Powers in view of Brown. 3/7/06 Office Action, p. 5.

The Examiner has noted that Powers fails to disclose or suggest "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1, from which claims 9-12 depend. *Id.* As discussed above, Brown also does not teach or suggest this limitation. Thus, it is respectfully submitted that neither Powers nor Brown, either alone or in combination, discloses or suggests "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1. In addition, it has been noted that Brown does not relate to medical devices and is incompatible with anatomical pressures to which the claimed invention relates. Thus, one skilled in the art would not be motivated to combine Brown with Powers, which relates to vascular access catheters. However, as described above, it is respectfully submitted that claims 9-12 are allowable even if these references are combined, as neither shows or suggests the recited biasing member.

Claim 16 recites limitations substantially similar to those of claim 1, including "*a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to*

*the closed position.*" Thus, it is respectfully submitted that claim 16 is allowable for at least the same reasons discussed above with reference to claim 1. Because claims 18, 22-27, 30, 32 and 34 depend from, and, therefore include all of the limitations of claim 16, it is respectfully submitted that these claims are also allowable.

Claims 19-21 and 28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Powers in view of Brown and in further view of Cushman. 3/7/06 *Office Action*, p. 7.

As discussed above, neither Powers nor Brown teaches or suggests "a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position," as recited in claim 16, from which claims 19-21 and 28 depend. It is respectfully submitted that Cushman does not cure the deficiencies of Powers and Brown and that neither Powers, nor Brown nor Cushman, either alone or in combination, discloses or suggests "a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position," as recited in claim 16 and claims 19-21 and 28 are allowable.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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